



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,461	07/10/2001	Yuan-Tsong Chen	2984.1000-004	6796

21005 7590 06/03/2003

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 06/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,461

Applicant(s)

CHEN, YUAN-TSONG

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "periodically" is vague and indefinite. If one were to administer a drug periodically when would that be ? Would one administer the drug every hour, every week, every month ? Periodically could be anything. Once in a while, when is that ?

Claim Rejections - 35 USC § 102

Claims 1-4, 9, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuller et al. ref. AV2.

Applicant argues that Fuller does not teach administering the acid alpha-glucosidase (GAA) to a human individual. Applicant also argues that Fuller does not teach administering the GAA periodically. Finally applicant argues that Fuller does not teach treatment of cardiomyopathy.

Fuller does teach that they believed that the GAA would be a useful candidate for replacement therapy in Glycogenosis type II (GSD II) patients, page 908, second column. Further, Fuller makes it clear that GSD is an autosomal recessive lysosomal storage disease that results from a deficiency of GAA. Thus, it is clear that they teach to administer the enzyme to treat the disease. The disease is known to lack the enzyme and they administer the enzyme to treat the disease, thus it is clearly taught to administer the GAA to such a human patient.

Enzyme replacement therapy is commonly done over a period of time. It is inevitable that one reading Fuller would periodically administer GAA to a human patient since one routinely does so when administering any kind of enzyme replacement therapy. For applicant to suggest that one of ordinary skill in the art would only administer the GAA once is simply false on its face. Absolutely no medical doctor would administer a drug once expecting it to treat the disease in its entirety.

Applicant lastly argues that Fuller does not treat cardiomyopathy with the GAA but the fact of the matter is claim 21 only requires that the "human individual" has glycogen storage disease type II which Fuller does teach.

Claim Rejections - 35 USC § 103

Claims 1-7, 11-18, 21 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuller et al. ref. AV 2.

The declaration has been considered but it is clear as stated above that Fuller clearly teaches administration of the enzyme to a human patient for the claimed purpose. Applicant offers no new arguments here.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al. ref. AV2

While Fuller may not explicitly teach using an immunosuppressant with the GAA to treat the disease it would have been obvious to do so since one would want to administer an immunosuppressant before administering the GAA so that the body would be less likely to reject the GAA and more readily use the GAA to treat the disease.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijvoet et al. ref AR 2 in view of Fuller et al. ref. AV2.

Applicant has essentially argued what is discussed above concerning Fuller. In fact, Bijoet teaches that the therapeutic potential of the recombinant enzyme produced in milk is demonstrated in vitro and in vivo. Further, this rejection was made with a combination of references and Bijoet is not expected to contain all of the claims limitations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Application/Control Number: 09/902,461
Art Unit: 1654

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
May 23, 2003